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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/580,742 | CAI ET AL. | |
| | Examiner | Art Unit | |
| | DAVID P. RASHID | 2624 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-44 is/are pending in the application.
 - 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 1-44 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____ . | 6) <input type="checkbox"/> Other: ____ . |

DETAILED ACTION

Table of Contents

| | |
|--|----|
| Prior Art | 2 |
| General Information Matter | 2 |
| Claim Status | 2 |
| Claim Rejections - 35 U.S.C. § 112 | 3 |
| Failure to Particularly Point Out and Distinctly Claim | 3 |
| Lack of Antecedent Basis | 3 |
| Claim Rejections - 35 U.S.C. § 101 | 4 |
| In Re Bilski – “Tied To” Criteria and/or Qualifying “Transformation” | 4 |
| Claim Rejections - 35 U.S.C. § 102 | 5 |
| Young | 5 |
| Claim Rejections - 35 U.S.C. § 103 | 10 |
| Young in view of Cheng | 10 |
| Young in view of Aylward | 11 |
| Conclusion | 12 |
| Citation of Pertinent Prior Art | 12 |

Prior Art

| | |
|---|----|
| U.S. Patent No. 6,309,353 (issued Oct. 30, 2001, hereinafter ‘Cheng’) | 9 |
| U.S. Pub. No. 2003/0053697 (published Mar. 20, 2003, hereinafter ‘Aylward’) | 10 |
| U.S. Pub. No. 2003/0056799 (published Mar. 27, 2003, hereinafter ‘Young’) | 4 |

General Information Matter

- [1] Please note, the instant Non-Provisional application (10/580742) under prosecution at the United States Patent and Trademark Office (USPTO), has been assigned to Art Unit 2624. Please ensure, to aid in correlating any papers for 10/580742, all further correspondence regarding the instant application should be directed to Art Unit 2624.
- [2] 10/580742 has been assigned to David Rashid (Examiner) in the Art Unit 2624 at the USPTO. To aid in correlating any papers for 10/580742, all further correspondence regarding the instant application should be directed to David Rashid in Art Unit 2624.

Claim Status

- [3] Claims 1-44 pending.

Claim Rejections - 35 U.S.C. § 112

- [4] The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-10, 16-35, and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Failure to Particularly Point Out and Distinctly Claim

Claim 30 cites “normalizing the intensity” but it is unclear whether said intensity is the volume intensity of the maximum intensity within the vessel lumen.

Lack of Antecedent Basis

Claims 2-10, 16-35, and 44 recites the limitations
“the boundary information” and “the multi-level vesselness” at claim 2;
“the vesselness response” at claims 4 and 19;
“the multi-level vesselness computation portion” at claim 9;
“the boundary information of objects” at claim 10;
“the multi-level vesselness” and "the edgeness" at claim 16;
“the computed vesselness” and “the computed edgeness” at claim 17;
“the intensity” at claim 22;
“the computation of multi-level vesselness” at claims 23 and 24;
“the edgeness” at claim 25;
“the vessel segmentation unit” at claims 26-29;
“the volume intensity”, “the maximum intensity”, “the body lumen”, “the maximum intensity of the volume”, and “the intensity” at claim 30;
“the edgeness filter” and “the boundary information” at claim 34;
“the front interface” at claim 35;
“the primary direction”, “the same scale”, and “the vesselness” at claim 36;
“the. . .speed volume” at claim 37;
“the user clicks” at claim 40; and

“the computed multi-level vesselness” at claim 44.

There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 U.S.C. § 101

[5] 35 U.S.C. § 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

In Re Bilski – “Tied To” Criteria and/or Qualifying “Transformation”

[6] **Claims 15, 17, 24, 27-29, 35, and 41** are rejected under 35 U.S.C. § 101 as not falling within one of the four statutory categories of invention. Supreme Court precedent¹ and recent Federal Circuit decisions² indicate that a statutory “process” under 35 U.S.C. § 101 must (1) be tied to another statutory category (such as a particular apparatus), or (2) transform underlying subject matter (such as an article or material) to a different state or thing. While the instant claim(s) recite a series of steps or acts to be performed, the claim(s) neither transform underlying subject matter nor positively tie to another statutory category that accomplishes the claimed method steps, and therefore do not qualify as a statutory process.

With regard to (1) above, a process must have either a meaningful tie to an “apparatus”, or “machine”, or the process must perform a qualifying transformation. Insignificant pre- or post-solution activity involving an “apparatus” or “machine” is not a meaningful tie. For example, claim 1 cites “receiving image data” which does not involve a machine (pre- or post-processing, or intended use statements are not significant to the inventive concept). In addition, when such machine is introduced and significant to the inventive concept, it must be a particular machine (e.g., a “processor”, not a “machine”).

With regard to (2) above, the image data in claim 1 does not represent a physical object that has been transformed prior to. The image data containing vessels may be pixel values

¹ *Diamond v. Diehr*, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876).

² *In re Bilski*, 88 USPQ2d 1385 (Fed. Cir. 2008).

creating what is regarded as a vessel, but not an actual physical vessel that has been transformed prior to.

Claim Rejections - 35 U.S.C. § 102

[7] The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Young

[8] **Claims 1-2** are rejected under 35 U.S.C. § 102(b) as being anticipated by Young.

Regarding **claim 1**, Young discloses a system for vessel segmentation (fig. 6), comprising:

at least one input adapter (fig. 10, item 91) for receiving image data;
a processor (fig. 10, item 92) in signal communication with the at least one input adapter;
a pre-processing unit (fig. 10, item 94) in signal communication with the processor for pre-processing the received image data; and
a vessel segmentation unit (fig. 10, item 95) in signal communication with the processor for segmenting vessels using pre-processed data.

Regarding **claim 2**, Young discloses wherein the image data is a computerized tomographic angiography ("CTA") data set (¶0071), the pre-processing unit (fig. 10, item 94) comprising:

a CTA pre-filtering portion (fig. 10, item 94) in signal communication with the processor for pre-filtering (“filter-based approaches” at ¶0004; “multi-scale filtering” at ¶0053) the CTA data set (¶0071);

an edgeness filtering portion (fig. 10, item 94) in signal communication with the processor for calculating the boundary information (e.g., fig. 6, items 1, 17; fig. 9, item 8); and

a multi-level vesselness computation portion (fig. 10, item 94) in signal communication with the processor for computing the multi-level vesselness (“the selection which model of which neighboring point fits best to the object. . .” at ¶0015; “cylinder model 48 fits best to the object 1. . .” at ¶0061).

Regarding **claim 4**, Young discloses wherein the CTA pre-filtering portion (fig. 10, item 94) is automatic for enhancing the vesselness response (e.g., calculating boundary information enhances the vesselness response; fig. 6, items 1, 17) in CTA data sets (¶0071).

Regarding **claim 5**, Young discloses wherein the CTA pre-filtering portion (fig. 10, item 94) is responsive to anatomic regions (fig. 6, item 1, 17) that are at least one of specified by a user and automatically determined (the boundary information items 1, 17 of fig. 6 are automatically determined).

Regarding **claim 6**, Young discloses wherein every voxel (e.g., cylinder items 40, 42, 47-48) in the CTA dataset can be pre-assigned with a probability (“the selection which model of which neighboring point fits best to the object. . .” at ¶0015; “cylinder model 48 fits best to the object 1. . .” at ¶0061 is indicative of probability) of being part of a vessel (fig. 6, item 1; ¶0003).

Regarding **claim 7**, Young discloses wherein the pre-assigned probability of a voxel being part of a vessel (“the selection which model of which neighboring point fits best to the object. . .” at ¶0015; “cylinder model 48 fits best to the object 1. . .” at ¶0061 is indicative of probability) is determined by at least one of three-dimensional (“3D”) shape (fig. 6, item 48 is three-dimensional), voxel intensity, derivatives of the intensity, and texture.

Regarding **claim 8**, Young discloses wherein the multi-level vesselness computation portion (fig. 10, item 94) uses vesselness (“the selection which model of which neighboring point fits best to the object. . .” at ¶0015; “cylinder model 48 fits best to the object 1. . .” at ¶0061) as a vessel enhancement method in CTA data sets to improve segmentation.

Regarding **claim 9**, Young discloses further comprising a display adapter (110) (fig. 10, item 93) in signal communication with the processor (fig. 10, item 92) for providing a visualization of vasculature responsive to the multi-level vesselness computation portion.

Regarding **claim 10**, Young discloses wherein the edgeness filtering portion (“filter-based approaches” at ¶0004; “multi-scale filtering” at ¶0053) computes the boundary information of objects (e.g., fig. 6, items 1, 17; fig. 9, item 8).

Regarding **claim 11**, Young discloses the vessel segmentation unit (fig. 10, item 95) having an integration portion for integrating vesselness and edgeness information (¶0052 wherein the adapted models are meshed; claim 10) to segment vessels using vesselness and edgeness.

Regarding **claim 12**, Young discloses wherein the vessel segmentation unit (fig. 10, item 95) provides a separation of vasculature from non-vasculature such as bones (“bones” at ¶0073) and soft tissue.

Regarding **claim 13**, Young discloses wherein the vessel segmentation unit (fig. 10, item 95) provides a segmentation of vasculature and other objects similar to vessels or tubes (“bones” at ¶0073 are similar to tubes), such as a spinal column.

Regarding **claim 14**, Young discloses wherein the vessel segmentation unit (fig. 10, item 95) provides a segmentation of non-vasculature such as bones and soft tissue (“bones” at ¶0073 are similar to tubes).

Regarding **claim 15**, Young discloses a method of vessel segmentation (fig. 6), comprising:

receiving image data (“image data” at fig. 1; fig. 10, item 91);
pre-processing (¶¶0060-0061) the received data; and
segmenting vessels (¶¶0060-0062) responsive to the pre-processed data.

Regarding **claim 16**, Young discloses wherein:

the image data (“image data” at fig. 1; fig. 10, item 91) is a computerized tomographic angiography ("CTA") data set (¶0071); and

pre-processing includes at least one of pre-filtering the received data, computing the multi-level vesselness (“the selection which model of which neighboring point fits best to the

object. . .” at ¶0015; “cylinder model 48 fits best to the object 1. . .” at ¶0061), and computing the edgeness.

Regarding **claim 17**, Young discloses wherein segmenting vessels (fig. 6) is responsive to the computed vesselness and to the computed edgeness (¶0052 wherein the adapted models are meshed; claim 10).

Regarding **claim 19**, claim 4 cites identical features as in claim 19. Thus, references/arguments equivalent to those presented above for claim 4 are equally applicable to claim 19.

Regarding **claim 20**, claim 5 cites identical features as in claim 20. Thus, references/arguments equivalent to those presented above for claim 5 are equally applicable to claim 20.

Regarding **claim 21**, claim 6 cites identical features as in claim 21. Thus, references/arguments equivalent to those presented above for claim 6 are equally applicable to claim 21.

Regarding **claim 22**, claim 7 cites identical features as in claim 22. Thus, references/arguments equivalent to those presented above for claim 7 are equally applicable to claim 22.

Regarding **claim 23**, claim 8 cites identical features as in claim 23. Thus, references/arguments equivalent to those presented above for claim 8 are equally applicable to claim 23.

Regarding **claim 24**, claim 9 cites identical features as in claim 24. Thus, references/arguments equivalent to those presented above for claim 9 are equally applicable to claim 24.

Regarding **claim 25**, claim 10 cites identical features as in claim 25. Thus, references/arguments equivalent to those presented above for claim 10 are equally applicable to claim 25.

Regarding **claim 26**, claim 11 cites identical features as in claim 26. Thus, references/arguments equivalent to those presented above for claim 11 are equally applicable to claim 26.

Regarding **claim 27**, claim 12 cites identical features as in claim 27. Thus, references/arguments equivalent to those presented above for claim 12 are equally applicable to claim 27.

Regarding **claim 28**, claim 13 cites identical features as in claim 28. Thus, references/arguments equivalent to those presented above for claim 13 are equally applicable to claim 28.

Regarding **claim 29**, claim 14 cites identical features as in claim 29. Thus, references/arguments equivalent to those presented above for claim 14 are equally applicable to claim 29.

Regarding **claim 31**, Young discloses pre-filtering comprising categorizing the CTA data (¶0071) into three ranges (e.g., image data within vessel, outside vessel, on boundary).

Regarding **claim 33**, Young discloses wherein pre-filtering is set up as a roof-shaped curve (e.g., fig. 6, item 17 has roof-shaped curve structure).

Regarding **claim 41**, Young discloses further comprising automatically extracting vessels (fig. 6, item 1) in accordance with basic knowledge of anatomy responsive to at least one of approximate direction (e.g., fig. 2b, item 2), curvature, and connectivity to other vessels.

Regarding **claim 42**, Young discloses wherein the image data ("image data" at fig. 1; fig. 10, item 91) includes a data set obtained from at least one of computerized tomographic angiography ("CTA"), magnetic resonance angiography ("MRA") ("MRA" at ¶0002), x-ray angiography ("XRA") and digital subtraction angiography ("DSA").

Regarding **claim 43**, Young discloses a program storage device readable by machine (fig. 10, item 92), tangibly embodying a program of instructions executable by the machine (¶0001) to perform program steps for vessel segmentation (fig. 6; fig. 8), the program steps comprising:

receiving image data ("image data" at fig. 1; fig. 10, items 90-91);
filtering ("filter-based approaches" at ¶0004; "multi-scale filtering" at ¶0053) the received image data;

computing multi-level vesselness ("the selection which model of which neighboring point fits best to the object . . ." at ¶0015; "cylinder model 48 fits best to the object 1 . . ." at ¶0061) of the filtered image data;

computing edgeness (fig. 6, item 17; fig. 9, item 8) of the filtered image data;

segmenting at least one vessel (e.g., fig. 8 vessel has been segmented; “combining all the models to create a single deformable model for the selected vessel segment” at ¶0035) in response to the computed vesselness and edgeness.

Regarding **claim 44**, Young discloses a program storage device as defined in claim 43, the program steps further comprising segmenting a vessel (e.g., fig. 8 vessel has been segmented; “combining all the models to create a single deformable model for the selected vessel segment” at ¶0035) in correspondence with the computed multi-level vesselness for vesselness-based front propagation (“the selection which model of which neighboring point fits best to the object. . .” at ¶0015; “cylinder model 48 fits best to the object 1. . .” at ¶0061).

Claim Rejections - 35 U.S.C. § 103

[9] The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

[10] This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

Young in view of Cheng

[11] **Claim 34** is rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination between Young in view of Cheng.

Regarding **claim 34**, Young does not disclose wherein the edgeness filter computes the boundary information with a Gaussian filter.

Cheng discloses a method for tumor diagnosis by measuring and evaluating three dimensional images (fig. 1) that teaches wherein an edgeness filter computes boundary information with a Gaussian filter (5:34-48).

It would have been obvious to one of ordinary skill in the art at the time the invention was made for the edgeness filter of Young to compute the boundary information with a Gaussian filter as taught by Cheng “to extract the exact boundaries of the tumor and show the three dimensional structure of the tumors.” Cheng at 2:28-29.

Young in view of Aylward

[12] **Claims 36** are rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination between Young in view of Aylward.

Regarding **claim 36**, Young does not disclose wherein the vessel segmentation uses a single-scale Hessian filter to estimate the primary direction in correspondence with the same scale as used to calculate the vesselness.

Aylward discloses a method for tubular object image processing (fig. 4) that teaches wherein the vessel segmentation uses a single-scale Hessian filter (¶0063) to estimate the primary direction (“Hessian approximates the ridge’s tangent direction” at ¶0063) in correspondence with the same scale as used to calculate the vesselness.

It would have been obvious to one of ordinary skill in the art at the time the invention was made for the vessel segmentation of Young to use a single-scale Hessian filter to estimate the primary direction in correspondence with the same scale as used to calculate the vesselness as taught by Aylward as “there is a need for an improved system and method for stable, accurate, and fast representation and analysis of tubular objects in multi-dimensional images. The present invention provides a system and method for processing a multi-dimensional image containing at least one tubular object.” Aylward at ¶0007-0008.

Conclusion

Citation of Pertinent Prior Art

[13] The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6251072 B1; US 20010031920 A1; US 6343936 B1; US 20020097901 A1; US 20020136440 A1; US 6514082 B2; US 20030052875 A1; US 20030122824 A1; US 20030132936 A1; US 20030208116 A1; US 20040160440 A1; and US 20050169507 A1.

[14] Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID P. RASHID whose telephone number is (571)270-1578 and fax number (571)270-2578. The examiner can normally be reached Monday - Friday 7:30 - 17:00 ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bhavesh Mehta can be reached on (571) 272-7453. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*/David P. Rashid/
Examiner, Art Unit 2624*

/Bhavesh M Mehta/
Supervisory Patent Examiner, Art Unit 2624

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